510(k) SUMMARY FOR MR/X-ray HFD

MAR 2 3 2012

(As required by 21 CFR 807.92)

1. GENERAL INFORMATION

Establishment:	IMRIS Inc.
Address:	100-1370 Sony Place Winnipeg, Manitoba Canada, R3T 1N5
Registration Number:	3003807210
Contact Person:	Mr. Sanjay Shah QA and Regulatory Engineer Email: sshah@imris.com Phone: 1-204-480-7070 Fax: 1-204-480-7071
Date of Summary Preparation:	March 6, 2012
Device Name / Trade name	IMRIS MR/X-ray Head Fixation Device
Classification Name:	Neurosurgical head holder (skull clamp)
Classification Panel:	Neurology
Classification (CFR section):	21 CFR 882.4460
Class:	Class II
Product Code:	HBL

2. PREDICATE DEVICES

The MR/X-ray HFD system is substantially equivalent to the following predicate medical devices.

NAME OF THE DEVICE	510(K) NUMBER	DATE OF CLEARANCE	MANUFACTURER
IMRIS Head Fixation Device (HFD100)	K103493	Nov 29, 2010	IMRIS Inc.
MAYFIELD® MR/X-Ray Skull Clamp	K081401	Oct 8, 2008	Integra LifeSciences corporation
DORO® Radiolucent/MRI Compatible Cranial stabilization	K063494	May 21, 2007	Pro med instruments GmbH

3. DEVICE DESCRIPTION

The IMRIS MR/X-ray Head Fixation Device System (HFD) is an MR safe mechanical support system intended to be used in head, neck and spine surgery when rigid fixation is required for cranial stabilization. The IMRIS MR/X-ray HFD has been designed for use with intra-operative MR imaging, X-ray Fluoroscopy and CT imaging modality.

The IMRIS MR/X-ray HFD and its accessories are designed to immobilize the head during surgical procedures and support patient in the prone, supine or lateral positions. The IMRIS MR/X-ray HFD system is comprised of the table adapter, linkage system, skull clamp and skull pins. The IMRIS MR/X-ray HFD system can be used with either the operating room table or the angiography room table. The table adaptor is used to mount IMRIS MR/X-ray HFD on the table. The linkage system is used to mount the Skull Clamp to the table Adapter. The skull clamp (including 3 skull pins) is used to hold head and neck in a particular position during surgical procedures.

4. INDICATION FOR USE

The IMRIS MR/X-ray Head Fixation Device System is an MR safe mechanical support system which is used in head, neck and spine surgery when rigid fixation is required for cranial stabilization. The MR/X-ray HFD is indicated for use during utilization of imaging modalities such as intraoperative MRI, CT imaging, and C-Arm X-ray angiography.

5. COMPARISION TO PREDICATE DEVICES

Manufacturer	Integra LifeSciences Corporation	Pro med instruments GmbH	IMRIS Inc.	IMRIS Inc.
FDA 510(k) #	K081401	K063494	K103493	Subject Device
Trade/Device Name	MAYFIELD® MR/X-Ray Skull Clamp	DORO® Radiolucent/MRI Compatible Cranial Stabilization and Halo Systems and accessories	HFD100	MR/X-RAY HFD
Product Code	HBL	HBL	HBL	HBL
FDA Classification	21 CFR 882.4460	21 CFR 882.4460	21 CFR 882.4460	21 CFR 882.4460

Indication for use	The MAYFIELD® MR/X-Ray Skull clamp is placed on the patient's skull to hold their head and neck securely in a particular position when rigid fixation is desired. The clamp is indicated for use in open and percutaneous craniotomies as well as spinal surgery when rigid fixation is necessary. In addition, the clamp is indicated for use during utilization of imaging modalities such as intraoperative CT and MR imaging, C-Arm X-ray, and digital subtraction techniques.	The Radiolucent MRI Compatible Skull Clamp Headrest System with Skull Pins The DORO® Radiolucent / MRI Compatible Skull Clamp Headrest System with Skull Pins are components of a mechanical support system which is used in head and neck surgery when rigid skeletal fixation is required for cranial stabilization and when intra-operative CT or MR Imaging is used. The Radiolucent / MRI Compatible Horseshoe Headrest System The DORO® Radiolucent / MRI Compatible Horseshoe Headrest System are components of a mechanical support system which is used in head and neck surgery when non-invasive head support is required and when intra-operative CT or MR Imaging is used.	The IMRIS Head Fixation Device System is an MR compatible mechanical support system which is used in head, neck and spine surgery when rigid fixation is required for cranial stabilization.	The IMRIS MR/X-ray Head Fixation Device System is an MR safe mechanical support system which is used in head, neck and spine surgery when rigid fixation is required for cranial stabilization. The MR/X-ray HFD is indicated for use during utilization of imaging modalities such as intraoperative MRI, CT imaging, and C-Arm X-ray angiography.

6. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE: (807.92 (A) (6))

CHARACTERISTIC	Integra LifeSciences Corporation MAYFIELD® MR/X-Ray Skull Clamp (K081401)	Pro med instruments GmbH DORO® Radiolucent/MRI Compatible Cranial Stabilization and Halo Systems and accessories (K063494)	IMRIS Inc. IMRIS HFD100 (K103493)	IMRIS Inc. IMRIS MR/X-RAY HFD (Current submission)	COMPARISION
Skull Clamp	3-Pin Skull clamp	3-Pin Skull clamp	3-Pin Skull clamp	3-Pin Skull clamp	Same
MRI system Compatibility	MRI compatible	MRI compatible	MRI compatible	MRI safe	Same
Used with Imaging Modality	Intraoperative CT and MR imaging, C-Arm X-ray, and digital subtraction	Intra-operative CT or MR	Intraoperative MRI	Intraoperative MRI, CT imaging, and C-Arm X-ray angiography.	Same as Integra and Pro med
Material	Composite materials	NOVOTEX laminated fabric with phenolic resin (GRP) colored with BASANTOL black X82 liquid and POM (Delrin), PEEK and Polyurethan	Titanium, Teflon coated fiberglass phenolic composites and Acetol (POM)	PEEK, Teflon, Cast Acrylic	Different
Mounting	Two pin mounting mechanism On Standard OR Table	Two pin mounting mechanism On Standard OR Table	Two pin mounting mechanism On IMRIS design OR table or Angio table	Two pin mounting mechanism On IMRIS design OR table or Angio table	Same as HFD100
Support load	20kg	12.5kg	20kg	20kg	Same
Pin force	80lb	80lb	80lb	80lb	Same
Application	General neurosurgical procedures	General neurosurgical procedures	General neurosurgical procedures	General neurosurgical procedures	Same
	Intra-operative neurosurgical procedures	Intra-operative neurosurgical procedures	Intra-operative neurosurgical procedures	Intra-operative neurosurgical procedures	Intra-operative neurosurgical procedures

CHARACTERISTIC	Integra LifeSciences Corporation MAYFIELD® MR/X-Ray Skull Clamp (**K081401**)	Pro med instruments GmbH DORO® Radiolucent/MRI Compatible Cranial Stabilization and Halo Systems and accessories (**K063494**)	IMRIS Inc. IMRIS HFD100 (**K103493**)	IMRIS Inc. IMRIS MR/X-RAY HFD (**Current submission**)	COMPARISION
Sterile Pins	MAYFIELD@ Radiolucent Skull Pins A-2020 (FDA 510(k) # K021604)	DORO® Radiolucent Disposable Single-Use Skull Pins of Yttried Zirconium or Titanium are X-ray and MRI compatible. MR-Safe		MAYFIELD@ Radiolucent Skull Pins A-2020	Same (Exactly the same as Integra LifeSciences Corporation Pins)
	MAYFIELD® Titanium Disposable Child Skull Pin A1119 (FDA 510(k) # K072208)		MAYFIELD® Titanium Disposable Child Skull Pin A1119	MAYFIELD® Titanium Disposable Child Skull Pin A1119	
	MAYFIELD® Titanium Disposable Adult Skull Pin A1120 (FDA 510(k) # K072208)		MAYFIELD® Titanium Disposable Adult Skull Pin A1120	MAYFIELD® Titanium Disposable Adult Skull Pin A1120	
	MAYFIELD® Adult Skull Pin, Titanium A1121 (FDA 510(k) # K072208)		MAYFIELD® Adult Skull Pin, Titanium A1121	MAYFIELD® Adult Skull Pin, Titanium A1121	
	MAYFIELD® Child Skull Pin, Titanium A1122 (FDA 510(k) # K072208)		MAYFIELD® Child Skull Pin, Titanium A1122	MAYFIELD® Child Skull Pin, Titanium A1122	

7. SUMMARY OF NON-CLINICAL DATA

Biocompatibility of Pins:

The skull pins used in the MR/X-ray HFD are invasive. The biocompatibility of pins has been verified by Integra LifeSciences Corporation in K021604 and K072208.

There is no change made by IMRIS. Pins initially included are provided by Integra Life Sciences with their labeling. IMRIS does not relabel the pins. Pins are purchased from Integra LifeSciences Corporation directly.

Design Verification and Validation Test (Bench Testing)

The MR/X-ray HFD system passed the following tests and meets product specifications.

The tests include Usability requirements and workflow, Loading test, Third party accessories compatibility test, MRI compatibility test (MR image artifacts test, MR heating test), Radiolucency and Reliability test.

8. CONCLUSION

The MR/X-ray HFD has the same intended use and indications for use as the predicate devices. Performance data demonstrate safety and effectiveness of the MR/X-ray HFD with the new characteristics.

The IMRIS MR/X-ray HFD verification/validation results and performance/safety standard results show that the device is safe and effective and substantially equivalent to the currently available predicate devices, IMRIS HFD100, Integra LifeSciences MAYFIELD® MR/X-Ray Skull Clamp and Pro med instruments DORO® Radiolucent/MRI Compatible Cranial stabilization.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

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CANADA

MAR 2 3 2012

Re: K113748
Trade/Device Name: IMRIS MR/X-ray Head Fixation Device
Regulation Number: 21 CFR 882.4460
Regulation Name: Neurosurgical head holder (skull clamp)
Regulatory Class: II
Product Code: HBL
Dated: March 14, 2012
Received: March 15, 2012

Dear Mr. Shah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K113748

Indications for Use

510(k) Number (if known): K113748

Device Name: IMRIS MR/X-ray Head Fixation Device

Indications for Use:

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Prescription Use ____x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K113748